

REMARKS

I. Introduction

Applicant thanks the Examiner for pointing out that some references were inadvertently not submitted with the previous information disclosure statements. Applicant has filed a supplemental information disclosure statement providing these missing references.

II. Claim Objections

Claims 1, 6-7, 16 and 31-51 are objected to for various informalities. While Applicant does not agree with the Examiner's statements regarding the necessity of the amendments requested, Applicant has made the requested amendments, as they do not have any effect on the scope of the claims.

III. Claim Rejections under 35 U.S.C. § 112

A. Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 16, 31-37, 39 and 45-51 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states these claims contain new matter, namely the recitation of various proteins that confer insect resistance in plants: Cry2, Cry9, and Vip3A. Office Action, p. 3. While the Examiner notes Applicants pointed to various patents incorporated by reference in the Specification in the Preliminary Amendment filed August 2, 2007, the Examiner states the cited patents are not present at the cited locations, speculating that Applicant and Examiner are referring to differently-paginated versions of the Specification. *Id.* pp. 3-4. Applicants respectfully traverse these rejections.

In order to ensure Applicant and Examiner are "on the same page," so to speak, references herein to patents incorporated by reference shall be to the published version of the instant application, US 2008/0226753 A1, published on September 18, 2008.

As an initial matter, all patents cited in the Specification are specifically incorporated by reference. *See* Specification, p. 8, ¶ [0075]. Material in publications or patents incorporated by reference "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." *See* MPEP § 2163.07(b). Thus, if support exists for these three proteins in patents or other publications incorporated by reference, the amendments are not new matter, and the written description requirement is satisfied.

Support for the Cry2 protein is found in at least U.S. Patent No. 6,023,013, col. 4, ll. 37-42. This patent is cited (and therefore incorporated by reference, as noted previously) in the Specification at page 2, ¶ [0011], l. 5. Support for the Cry9 protein is also found in U.S. Patent No. 6,023,013, at col. 4, l. 63 - col. 5, l. 1. Support for the Vip3A protein is found in at least U.S. Patent No. 5,877,012, col. 2, ll. 50-58. This patent is cited (and therefore incorporated by reference, as noted previously) in the Specification at page 2, ¶ [0015], l. 7. As such, each of these proteins finds support in the Specification, and their inclusion in the claims does not violate the written description requirement.

The Examiner further contends that because these patents are mentioned in the "Background" section as opposed to the "Summary of the invention" section, they cannot provide support for the toxins even if incorporated by reference. *See* Office Action, p. 4. The Examiner cites no authority for this proposition. Of course, this is not the law, as the written description support is examined "in view of the disclosure of the application as filed," not a particular

portion of the application. *See* MPEP § 2163.04(I)(B) (emphasis added); *see also* 35 U.S.C. § 112 (stating that the "specification" must contain the required written description); *SafeTCare Mfg., Inc. v. Tele-Made, Inc.*, 497 F.3d 1262, 1269 (Fed. Cir. 2007) (stating the "Background" section is part of the written description); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1378 (Fed. Cir. 2005) (same); *cf. Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1374 (Fed. Cir. 2005) ("A patent specification may sufficiently enable a feature under § 112, ¶ 1, even if only the background section provides the enabling disclosure.").

B. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 2-3, 14, 17-18 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Specifically, the Examiner objects to the use of various acronyms in the claims, including ECB, WCRW, GAT, and EPSPS.

Applicant respectfully submits that one of ordinary skill in the art would understand the meaning of these acronyms. Specifically, the specification states ECB is the acronym for European corn borer. *See* Specification, p. 1, ¶ [0004]. WCRW is the acronym for western corn rootworm. *Id.* ¶ [0011]. GAT is known to be glyphosate N-acetyltransferase, a gene conferring tolerance to glyphosate herbicide. Finally, EPSPS is commonly known to be 5-enolpyruvylshikimate-3-phosphate synthase.

While those in the art are familiar with these acronyms, Applicant has amended the relevant claims to replace the acronym with the full name of the pest or gene, as appropriate. Applicant notes that these amendments do not change the scope of the claims as originally

drafted. In light of these clarifying amendments, Applicant respectfully requests the rejection of these claims be withdrawn.

IV. Claim Rejections under 35 U.S.C. § 103

A. Rejection of Claims 1, 4, 16, and 19 over Zhao

Claims 1, 4, 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao et al. (2003, *nature Biotechnol.* 21:1493-1497). Office Action, pp. 5-6. Specifically, the Examiner states that because Zhao states there is no linkage between Cry1Ac and Cry1C resistance in diamondback moths, Cry1Ac and Cry1C operate via different modes of action. *Id.* Further, although the Examiner admits Zhao does not teach planting a blend of seeds of the plants, the Examiner states these claims would be obvious, asserting one in the art "would have been motivated to do so because seeds are what farmers would plant in the fields." *Id.* p. 6. Applicant respectfully traverses this rejection.

Even assuming the Examiner's assertion regarding Zhao is correct and that Cry1Ac and Cry1C proteins operate via a different mode of action, Zhao provides no reason to plant a blend of seeds that express these two proteins. In fact, Zhao teaches away from the claimed method. For example, Zhao observes there are at least four possible ways to delay resistance in *Bt* crops: (i) non-high dose; (ii) high dose + refuge; (iii) deploying different toxins individually in different varieties; and (iv) pyramiding, or deploying two or more toxins in a single plant. *See* Zhao, p. 1493, left column, second paragraph. Of these, Zhao states "the refuge—high dose (ii) and pyramiding (iv) strategies seem most promising." *Id.* Further, Zhao states "allowing the concurrent release of cultivars with the two *Bt* genes in separate plants, each with one *Bt* gene, is

not the best way to delay resistance." *Id.* p. 1495, right column, first full paragraph. Zhao concludes that the pyramiding strategy is the strategy that should be pursued, stating:

stacking or pyramiding toxin genes that express toxins with different modes of action or binding characteristics at a "high" dose offers a potential route for achieving longer delays in the development of resistance. We believe that industry should be encouraged to develop such plants for their increased durability for insect management and we suggest that the smaller refuge size required by pyramided toxin plants may be an additional incentive to do so.

Id. p. 1496, left column, first full paragraph.

These statements teach away from the method provided in claims 1, 4, 16, and 19. These claims are directed to what Zhao states is inferior: planting two different plants with a different *Bt* gene in each. *See* Claim 1, 4, 16, 19. As such, one of ordinary skill in the art would be dissuaded from utilizing the claimed seed blends, given that Zhao characterizes them as inferior to a pyramiding strategy for resistance management. *See* MPEP § 2141.02(V). As such, there is no reason why one of ordinary skill in the art would modify Zhao in the manner suggested by the examiner. Accordingly, Applicant submits the rejection is in error and should be withdrawn.

B. Rejection of Claims 5 and 20 over Zhao in view of Pershing

Claims 5 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of Pershing et al. (US Patent No. 6,551,962). Specifically, the Examiner combines the previously-discussed application of Zhao with the teaching of Pershing to treat seed transformed to produce a Cry3Bb protein with pesticidal agents. *See* Office Action, pp. 6-7. Applicant respectfully traverses this rejection.

As described above, Zhao teaches away from using a seed blend as claimed in independent claims 1 and 16. As such, the rejection of claims 5 and 20, which depend from

claims 1 and 16 respectively, also cannot be supported by the Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

C. Rejection of Claims 14 and 29 over Zhao in view of Plaisted

Claims 14 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of Plaisted et al. (1999, US 5,990,395). Specifically, the Examiner combines the previously-discussed application of Zhao with the teaching of Plaisted of plants with a Cry1Ab gene and an EPSPS gene. *See* Office Action, p. 7. Applicant respectfully traverses this rejection.

As described above, Zhao teaches away from using a seed blend as claimed in independent claims 1 and 16. As such, the rejection of claims 14 and 29, which depend from claims 1 and 16 respectively, also cannot be supported by the Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

D. Rejection of Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 over Zhao in view of each of Crickmore, Pershing, and Narva

Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of each of Crickmore et al. (1998, Microbiol. Mol. Biol. Rev. 62:807-813), Plaisted, Pershing and Narva et al. (WO 97/40162), taken with the evidence of the instant application. Specifically, the Examiner combines the previously-discussed application of Zhao with Crickmore, which teaches the existence of several Cry proteins, Narva, which teaches Cry34Aa1 and Cry35Aa1, Plaisted, which teaches the combination of Cry1Ab or VIP3 with EPSPS, and Pershing which teaches

Cry3Bb proteins and treatment with pesticides. *See* Office Action, pp. 8-9. Applicant respectfully traverses this rejection.

As described above, Zhao teaches away from using a seed blend as claimed in independent claims 1 and 16. As such, the rejection of claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51, which directly or indirectly depend from either claim 1 or 16, also cannot be supported by the Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

Even assuming the Examiner's rationale regarding Zhao is correct, however, the rejection still cannot be maintained. As noted by the Examiner, Crickmore discloses the existence of numerous (over 100) different Cry proteins, with other Cry proteins disclosed in the other cited references. *See* Office Action, pp. 8-9; Crickmore, p. 809, Table 1. This is one of the paradigmatic situations where claims are not obvious. As recently stated by the Federal Circuit, a claim is not obvious when:

"what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."

In re Kubin, Slip Op. at 14 (Fed. Cir. Apr. 3, 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

This is exactly the logic the Examiner suggests renders the claims obvious: simply try each of the over 100 different Cry proteins in combination with any of the remaining Cry proteins (for a total of about 10,000 combinations) to determine which combinations would work the best. *See* Office Action, p. 9. The Examiner does not point to any guidance in the prior art as to which combinations are likely to be successful. Accordingly, the Federal Circuit has

unambiguously held this type of rejection is improper. As such, for at least this additional reason, Applicants respectfully submit the rejection is improper and should be withdrawn.

V. Conclusion

No fees or extensions of time are believed to be due in connection with this response; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kurt R. Van Thomme', enclosed within a large, loopy oval shape.

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